

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

By the present amendment, claims 114, 123-128, 130-132, and 137-141 are amended. Claims 142 and 143 are newly added. No claims are newly canceled. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. Support for the amended claims may be found throughout the specification as originally filed. Support for new claims 142 and 143 may specifically be found in claims 56 and 58 as originally filed.

After amending the claims as set forth above, claims 114-143 will be pending in this application, with claims 123-127 and 137-141 withdrawn from consideration as directed to a non-elected invention, and claims 1-113 having been canceled by previous amendment. Applicant submits that the amendment of claims 130-132, to specify that the percentages are based upon weight, renders moot the ground for objection as set forth in paragraph 5 of the Office Action.

I. Examiner Interview

As an initial matter, Applicant's Representatives, Steve Davis and Jeff Lomprey, thank Examiner Nerangis for taking the time for an interview of the present matter on October 2, 2009. The claims, recent office action, and cited references were discussed. The Examiner agreed that the rejections based upon Gross and Noda were overcome and would be withdrawn.

II. Response to Rejections Under 35 U.S.C. §§ 102(b)/103(a)

Claims 114-117, and 119-122 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over WO 97/07153, by Gross *et al.*

Claim 114 presently recites:

A blend comprising a first PHA and a second PHA,

wherein:

the first PHA is a copolymer consisting of a comonomer I-A and a comonomer I-B and the second PHA is a copolymer consisting of a comonomer 2-A and a comonomer 2-B;

the first PHA copolymer and the second PHA copolymer are the same copolymer, in which the ratio of comonomer I-A:comonomer I-B in the first PHA is different from the ratio of comonomer 2-A:comonomer 2-B in the second PHA.

As stated in the claim, the two PHA copolymers are the same binary compounds, differing in the ratio of the two co-monomers in the copolymers. Specifically, the claim language “consisting of” does not permit the presence of a third repeat unit. Applicant submits that Gross fails to teach or suggest such compounds, and further that Gross fails to enable one of skill in the art to prepare such blends of compounds.

Gross is directed to the use of polyethyleneglycol (PEG) with culture media in the preparation of polyhydroxyalkanoates (PHAs) to control their molecular weights and alter the PHA repeat unit sequence distribution. *See Abstract.* To effect this, *A. eutrophus* is grown on 4-hydroxybutyrate (4-HB), with the resulting PHA closely approximating a random co-polyester of 3HB and 4HB repeat units. Page 14, lines 16-18. When PEG (PEG-200) is added to the culture, the product mixture shifts to include 3-hydroxyvalerate (3HV) and ethylene glycol (EG) repeat units in the polymers. *See page 14, lines 20-31 and Table 1.* Under one set of conditions (e.g. culture condition A), 4HB becomes the predominant repeat unit, and under a different set conditions (e.g. culture condition B) 3HB becomes the predominant repeat unit. *See Table 1.* However, the materials prepared include the 3HV and EG repeat units. As stated by Gross on page 21:

To simplify the repeat unity sequence analysis below, the small contributions from 3HV and EG repeat units *were neglected* so that

the products *were assumed* to consist of only 3HB and 4HB repeat units.

Applicant submits that in view of the express teachings of Gross, there is no teaching or suggestion to prepare blends of two, or more, PHA copolymers, which are binary compounds, differing in the ratio of the two co-monomers in the copolymers. Gross prepares a copolymer that is high in 4HB content by culture condition A, and a copolymer that is high in 3HB content by culture condition B. However, there is no blend of the two prepared co-polymers. The polymers in the compositions of Gross, contrary to the requirements of the language of Claim 114, all contain more than two different repeat units, i.e., 3HB, 4HB, 3HV, and EG repeat units. Therefore, where the Examiner cites to the dyad sequence on page 25, lines 26-28, these are not copolymer compositions containing only 3HB and 4HB, they are *assumed* to have this composition for purposes of simplicity.

To the extent that the Examiner would argue that this is a suggestion by Gross to prepare such blends, Applicant argues to the contrary. Because the objective in Gross is to control the 3HB/4HB ratio by adding PEG to the culture medium, there is no motivation to omit PEG. Moreover, the fact remains that the cultures disclosed by Gross produce the mixtures with 3HB, 4HB, 3HV, and EG, and do not produce blends of 3HB:4HB copolymers at differing ratios. As such, there is no enablement in Gross for the production of the claimed blends of PHA materials.

Furthermore, with respect to claims 119 and 120 that recite elements such as “a deformation angle tolerance of at least about 5°,” and “a thermal deformation resistance temperature of at least 80°C,” respectively, there is no teaching or suggestion of these elements in Gross. Gross discusses how even small changes in the amount of PEG used can effect the PHAs produced by the methods (*see* page 14, lines 25-28), and incorporation of alkyl side chains into a PHA can have a dramatic effect on the physical properties. For example, as shown by Gross, P3HB has a T_m of 177°C compared to that of P4-HB at 54°C. *See* page 24, lines 11-12. In other words, one methyl side chain group changes the T_m of a compound by over 120°C!

Because the materials prepared by Gross are not the same as the presently claimed PHA blends, physical properties of the claimed PHA blends, such as deformation angle and deformation resistance, were unknown to Gross and are not readily predictable. As stated by the Federal Circuit in *In re Rijckaert* “[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established.” *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). Based upon the dramatic shifts in properties with small chemical changes, there can be no assumption that the materials of Gross will exhibit the properties as claimed for example in claims 119 and 120.

Applicant submits that Gross fails to teach or suggest the same blends as are presently claimed, and that because the data pointed to by the Examiner in Gross is based upon ignoring the actual chemical makeup of the compounds, the presently claimed invention is readily distinguishable from Gross. As such, Applicant respectfully requests withdrawal of the noted rejections, and that the application be allowed to proceed to issuance.

III. Response to Rejections Under 35 U.S.C. § 103(a)

Gross

Claim 118 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Gross. As set forth above in section I, Applicant has shown that Gross fails to anticipate or render obvious the presently claimed invention, and Applicant submits that the rejection of claim 118 fails for the same reasons. Accordingly, Applicant traverses this rejection, and respectfully requests its withdrawal.

Noda

Claims 128-136 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. 6,808,795, issued to Noda *et al.* Applicant respectfully traverses this rejection.

Claim 128, from which each of claims 129-136 depends, presently recites:

A blend comprising a first PHA and a second PHA, wherein:
the first PHA is a poly(3-hydroxybutyrate) homopolymer; and the
second PHA is a copolymer having a first and a second
comonomer,
wherein the first co-monomer is 3-hydroxybutyrate and the second
comonomer is 4-hydroxybutyrate and the first PHA and the second
PHA are miscible or partially miscible.

Therefore, the blend contains a homopolymer (3-HB) and a copolymer (3HB:4HB) and the two copolymers are at least partly miscible in one another. As shown in the examples, the blends are prepared by dissolution of the polymers and subsequent removal of the solvent. Dependent claims provide additional details with respect to the amounts of the compounds in the blend and copolymer and also details with respect to the physical properties exhibited by the blends, such as the deformation angle tolerance and the thermal deformation resistance temperature. Applicant submits that Noda fails to teach or suggest such a composition, or such properties.

Noda is directed to PHA copolymers with polylactic acid (PLA) and other PLA copolymers for the preparation of biodegradable films and laminates. *See* col. 1, lines 10-16. Noda discloses environmentally degradable polymers of a first polymer that is a polyhydroxyalkanoate copolymer, and a second polymer that is a PLA polymer. *See* Col. 3, lines 53-57. In describing the interaction of the materials, Noda states:

If a second polyhydroxyalkanoate copolymer is used as described above, a majority of the PHA composition comprises the first biodegradable polyhydroxyalkanoate copolymer, whereby the second biodegradable PHA is *finely dispersed* throughout a continuous phase or matrix of the first copolymer and is included in an amount sufficient to improve the crystallization rate and/or physical properties of the first copolymer.

Col. 6, lines 6-12. In other words, Noda is stating that the second PHA is a solid that is dispersed within the first PHA, and acts as a nucleant for the first PHA to improve crystallization. However, Noda differs from the presently claimed invention in at least two ways.

First, there is no teaching or suggestion in Noda that the first PHA and the second PHA are miscible in one another to any extent. In fact, as shown from quotation reproduced above, Noda expressly teaches that the second PHA is finely dispersed in the first PHA, thereby improving the crystallization rate of the first PHA. From this expressed teaching, one of ordinary skill in the art would understand that the second PHA is a solid that can provide sites of nucleation for crystallization of the first PHA, and, as such is a nucleant that is entirely *immiscible* in the first PHA. In contrast, the language of claims 128, 142, and 143 require that the blend is either miscible or partially miscible.

Second, Noda fails to teach or suggest any of the properties described by claims 129-136, 142, and 143. Without a teaching or suggestion of the presently claimed blends in Noda or Scott, there can be no teaching or suggestion that such properties are inherent to the blends.

In view of the foregoing, Applicant submits that Noda simply fails to provide any guidance or reason to the person of ordinary skill in the art to prepare the claimed PHA blends. As such, Applicant respectfully requests withdrawal of the noted rejections, and that the present application be allowed to proceed to issuance.

IV. Request for Rejoinder of Withdrawn Claims

Applicant acknowledges the Examiner's withdrawal of claims 123-127 and 137-141 as directed to a non-elected invention. However, as explained above, after entry of the present communication, Applicant submits that the claims are now in condition for allowance. As claims 123-127 and 137-141 are related to the allowed claims as a method of making the allowed product, Applicant respectfully requests that the withdrawn claims be rejoined to the application and allowed to proceed to issuance.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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**The Commissioner is hereby authorized to charge any fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.